REMARKS

Applicants thank Examiner Smith for her time and helpful comments during a telephonic interview with the undersigned representative on April 4, 2006. The substance of the interview related to the rejections of the claims under 35 U.S.C. § 112, first paragraph (written description) and under 35 U.S.C. § 112, second paragraph. Possible claim amendments and arguments were discussed, but no agreement was reached.

Reconsideration of the present Application in view of the Amendment and Request for Continued Examination enclosed herewith and the following remarks is respectfully requested. Claims 58, 71, 73, and 74 are currently pending. Applicants have amended claims 58 and 71 and added new claims 75 and 76 to point out with greater particularity and distinctly claim certain embodiments of Applicants' invention. Support for the amended and new claims may be found throughout the specification, for example, at page 13, lines 1-8; page 29, line 24 through page 30, line 1; page 33, lines 1-8; page 31, lines 20-25; and at page 33, lines 10-13; page 35, lines 13-14. Table 4 (page 71) of the specification has been amended to point out with greater particularity that the first column lists cell surface marker antigen specificity of immunoglobulin molecules that were included in an exemplary array (*see* page 63, lines 21-24; *see also* page 62, lines 3-11; page 17, line 30 through page 18, line 7 (describing Figure 7, which is the graphic representation of the summary in Table 4)). No new matter has been added to the application. Upon entry of the amendments submitted herewith, claims 58, 71, and 73-76 will be pending.

Rejections Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 58, 71, 73, and 74 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Action asserts that the claims contain new subject matter that was not described in the specification. Specifically, the Action asserts that the specification does not adequately support the feature "antigen-binding derivatives."

Applicants respectfully traverse this rejection and submit that the present claims as amended herein are described in the instant specification in sufficient detail such that a person skilled in the art would appreciate that Applicants had possession of the claimed embodiments at the time the application was filed. Applicants further submit that no new matter has been introduced into the application.

Amended claim 58 relates, in pertinent part, to an assay device that comprises a solid support and an array of immunoglobulin molecules, and *antigen-binding fragments thereof.* The application describes at page 33, lines 10-13, that the immunoglobulin molecules of an array may be monoclonal or polyclonal antibodies or antigen-binding parts, which, for example, include Fab fragments. "Antigen-binding fragment" is a term with which a person skilled in the antibody art is quite familiar. The recitation that an array comprises immunoglobulin molecules or "antigen-binding fragments thereof," clearly conveys the meaning that an immunoglobulin molecule of an array may be a whole immunoglobulin or may be a portion of the immunoglobulin molecule that binds to the specific cognate antigen, that is, "an antigen-binding fragment" of the immunoglobulin molecule.

Thus, Applicants submit that each term recited in claim 58 does not constitute new matter and has adequate support in the specification, clearly conveying to a person skilled in the art that Applicants possessed the claimed assay device at the time the application was filed. Applicants therefore respectfully request that this rejection of claim 58, and claims dependent thereon, be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 58, 71, 73, and 74 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Action asserts that the feature "the cell surface marker antigens are selected from the list in Table 4" lacks written description in the specification.

Applicants respectfully traverse the basis for this rejection and submit that the specification reasonably conveys to a person skilled in the art that Applicants possessed the

claimed embodiments at the time the application was filed. Furthermore, in view of the amendments to Table 4 submitted herewith, a person skilled in the art would even more readily appreciate that Applicants were in possession of the claimed assay device at the time of filing.

As described in the specification and recited in the instant claims, the assay device comprises, in pertinent part, an array comprising different immunoglobulin molecules, or antigen-binding fragments thereof, that are specific for different cell surface marker antigens, wherein the binding pattern of the immobilized immunoglobulin molecules (or antigen-binding fragments thereof) to their respective cell surface antigens indicates the presence of cancer or the propensity to develop cancer (*see, e.g.,* page 13, lines 1-8; page 29, line 24 through page 30, line 1). In a specific embodiment, the different immunoglobulin molecules (or antigen-binding fragments thereof) are specific for different cluster of differentiation (CD) antigens that are expressed on leukocytes (*see, e.g.,* page 13, lines 1-8; page 32, line 27 through page 33, line 8; page 42, lines 14-22).

The specification further describes that an assay device for identifying a leukemia of T-cell, B-cell, or myeloid lineage in a subject may comprise immunoglobulin molecules, or antigen binding fragments thereof, that are specific for antigens selected from the list in Table 4. In a working example, the specification describes that different immunoglobulin molecules specific for different cell surface antigens were bound to a solid support to form an array (*see* pages 62-65 (Example 10)). As noted at page 63, lines 21-24, the results of an experiment are presented in Figure 7 and are summarized in Table 4. The brief description of Figure 7 states that the numbers denote antibodies that specifically bind to the relevant CD molecule (*e.g.,* "2" denotes anti-CD2) (*see* page 17, line 30 through page 18, lines 1-7: Brief Description of Figure 7; Figure 7).

Even though a person skilled in the art would readily understand that Table 4 summarizes the results of antibody binding to the specific antigen listed, to clarify with greater particularity that Table 4 presents a summary of the binding pattern of specific binding of anti-cell surface antigen antibodies to their respective cell surface antigens, the previous heading ("Antibody") of Table 4 has been amended to "Antibody Specificity/(Cell Surface Antigen)." In addition, in accordance with the brief description of Figure 7, "CD" has been added to precede

the CD antigen number in Table 4. Applicants submit that these amendments to Table 4 are supported in the description and, therefore, no new matter has been added to the application.

Accordingly, Applicants submit that the subject matter of claims 58, and claims dependent thereon, is adequately described in the specification, thus meeting the written description requirements under 35 U.S.C. § 112, first paragraph. Applicants therefore respectfully request that this rejection of claims 58, 71, 73 and 74 be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 58, 71, 73, and 74 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly lacking definiteness.

(1) The Action rejects claims 58 and claims dependent thereon, asserting that the term "derivatives" or "derivative" is vague and indefinite and that what a derivative of an immunoglobulin is intended to be is unclear.

Applicants respectfully traverse this ground for rejection and submit that when read in light of the specification, the terms are clear and definite. Nevertheless, to point out with greater particularity and to define with even more specificity, claims 58 and 71 have been amended to recite that an array comprises "immunoglobulin molecules, or *antigen-binding fragments thereof*." Support for this amendment may be found at page 33, lines 10-13.

Accordingly, Applicants submit that the present claims meet the requirements under 35 U.S.C. § 112, second paragraph, and respectfully request that this rejection be withdrawn.

(2) The Action rejects claim 58 and claims dependent thereon, alleging that the meaning of the phrase "different immunoglobulin molecules specific for different cell surface antigens" is unclear.

Applicants respectfully traverse the basis for this rejection and submit when read in light of the specification, the claimed subject matter meets the requirements for definiteness. As described in the specification and recited in the instant claims, the claimed assay device

comprises an array of immunoglobulin molecules (or antigen-binding fragments thereof) immobilized to a solid support. The array comprises discrete regions on the solid support, and each discrete region comprises immunoglobulin molecules (or antigen-binding fragment thereof) that are specific for a single distinct cell surface marker antigen on a leukocyte such that the array comprises different immunoglobulin molecules (or antigen-binding fragments thereof) that are specific for different cell surface marker antigens (*see, e.g.,* page 31, lines 24-26; page 32, line 27 through page 33, line 8; page 35, lines 9-18). The immunoglobulins (or antigen-binding fragments thereof) that are immobilized to the support are arranged in the array such that specific binding of each group of immunoglobulin molecules (or antigen-binding fragments thereof), located at each discrete region, to the respective distinct cell surface marker antigen on the leukocyte provides a pattern of expression of the cell surface marker antigens on the leukocyte, thus distinguishing leukemias of T-cell, B-cell, or myeloid lineage (*see, e.g.,* page 13, lines 1-8; page 33, lines 1-8; *see also, e.g.,* page 50, line 20 through page 51, line 12; Figure 3; Figure 7).

Therefore, when claim 58 is read as a whole in view of the disclosure in the specification, the claim, and claims dependent thereon, are clear and definite. Applicants submit that the present claims meet the requirements for definiteness under 35 U.S.C. § 112, second paragraph, and respectfully request that this rejection be withdrawn.

(3) The Action rejects claim 58, asserting that the feature, "the cell surface marker antigens are selected from the list in Table 4," lacks clarity and that the Table does not list cell surface marker antigens.

Applicants respectfully traverse the basis for this rejection and submit that amended Table 4 clarifies that Table 4 lists the cell surface marker antigen specificity of different immunoglobulin molecules (or antigen-binding fragments thereof). As described in the specification and recited in the instant claims, an assay device for identifying a leukemia of T-cell, B-cell, or myeloid lineage in a subject may comprise immunoglobulin molecules, or antigen binding fragments thereof, that are specific for cell surface marker antigens selected from the list in Table 4. In a working example, the specification describes that different immunoglobulin molecules specific for different cell surface antigens were bound to a solid

support to form an array (*see* pages 62-65 (Example 10)). As noted at page 63, lines 21-24, the results of an experiment are presented in Figure 7 and are summarized in Table 4. The brief description of Figure 7 states that the numbers denote antibodies to the relevant CD molecule (*e.g.*, "2" denotes anti-CD2) (*see* page 17, line 30 through page 18, lines 1-7: Brief Description of Figure 7; Figure 7). To clarify with greater particularity that Table 4 presents a summary of the pattern of specific binding of anti-cell surface antigen antibodies to their respective cell surface antigens, the previous heading ("Antibody") of Table 4 has been amended to "Antibody Specificity/(Cell Surface Antigen)." In addition, "CD" has been added to precede the CD antigen number in Table 4 (*see* page 18, lines 1-7).

Accordingly, Applicants submit that the present claims meet the requirements for definiteness under 35 U.S.C. § 112, second paragraph, and respectfully request that this rejection be withdrawn.

(4) The Action rejects claim 58, and claims dependent thereon, alleging that the feature, "the immobilized immunoglobulins," recited in line 10 of claim 58 has insufficient antecedent basis. The Action also rejects claim 58, alleging that the claim lacks clarity by reciting "the immunoglobulins, or antigen-binding fragments thereof" or "immunoglobulins."

Applicants respectfully traverse this rejection and submit that the feature, "the immobilized immunoglobulins," has sufficient basis in lines 3 and 4 of claim 58. Nevertheless, to point out with even greater clarity and to expedite prosecution of the application, claim 58 has been amended to recite at line 10 that "the immunoglobulins, or antigen-binding fragments thereof, that are immobilized to the support," which has specific antecedent basis in lines 3 and 4. In addition, all claims submitted herewith consistently recite that the array comprises "immunoglobulin molecules, or antigen-binding fragments thereof."

Accordingly, Applicants submit that the present claims meet the requirements for definiteness under 35 U.S.C. § 112, second paragraph, and respectfully request that this rejection be withdrawn.

(5) The Action rejects claims 71, 73, and 74, asserting that the feature, "the immunoglobulins, or derivatives thereof" recited in claim 71 and the feature "the immunoglobulin molecules" recited in claims 73 and 74 lack antecedent basis.

Applicants submit that in view of the amendments submitted herewith, claims 71, 73, and 74 meet the requirements for definiteness. Amended claim 71 relates to the assay device, wherein the "immunoglobulin molecules, or antigen-binding fragments thereof, of the array are immobilized to the solid support by covalent binding to the solid support or wherein the immunoglobulin molecules, or antigen-binding fragments thereof, of the array are immobilized to the solid support by binding to a recombinant, truncated protein G that is first coated on the solid support." Thus, all claims consistently recite that "immunoglobulin molecules, or antigen-binding fragments thereof" are immobilized to the solid support.

Accordingly, Applicants submit that the present claims meet the requirements for definiteness under 35 U.S.C. § 112, second paragraph, and respectfully request that this rejection be withdrawn.

Applicants submit that claims 58, 71, and 73-76 in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned at 206-622-4900.

Respectfully submitted,

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